

Appl. No. 10/717,559  
Amendment dated: September 5, 2007  
Reply to OA of: June 20, 2007

### **REMARKS**

Applicants have amended the specification and claims to more particularly define the invention taking into consideration the outstanding Official Action. Applicants have canceled claims 1-5 from the present application without prejudice or disclaimer. Applicants have amended claims 6 and 13 to more particularly define the invention. Applicants note that Applicants election without traverse of Group I, namely claims 1-13, in the reply filed on April 23, 2007 is acknowledged. Claims 14-23 are drawn to a non-elected invention and have been cancelled in the reply filed on April 23, 2007. Applicants retain their right to file a divisional application at a later time to the non-elected invention. Applicants submit that the claims now present in the application are fully supported by the specification as originally filed and no new matter is introduced.

The objection to the abstract of the disclosure because of several typographical errors set forth on page 3 of the outstanding Official Action has been carefully considered but is most respectfully traversed in view of the amendments to the abstract of the disclosure and the following comments.

Applicants have added the word "the" prior to "human body" in line 3 of the abstract in accordance with the Examiner's helpful suggestion. It is stated that "lanostane" in line 3 of the abstract is spelled incorrectly. However, Applicants have carefully reviewed the abstract of the disclosure as originally filed and most respectfully submit that the word "lanostane" is not misspelled in the present application. It is further stated that in line 4, "metabolite" is spelled incorrectly and in line 6, "the" is spelled incorrectly. Applicants have further carefully reviewed the abstract of the disclosure as originally filed with respect to the spelling of "metabolite" in line 4 and "the" in line 6 and most respectfully submit that these words are not misspelled.

Further, upon review of the USPTO's IFW, Applicants note that it appears the letter "e" in "lanostane", "metabolite", and "the" is missing in the scanned image of the abstract of the disclosure thus making the words appear to be misspelled as stated in

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the outstanding Official Action. Therefore, Applicants submit herewith a copy of the Abstract of the Disclosure as originally filed which shows that the words "lanostane", "metabolite" and "the" are spelled correctly. Accordingly, it is most respectfully requested that this objection be withdrawn.

The rejection of claims 1-2 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention has been carefully considered but is most respectfully traversed in view of the cancellation of claims 1-2 from the present application, the amendment to claim 13 and the following comments.

With respect to the formula (I) which is objected by the Examiner in the due to the carbon atoms at positions 8 and 9 being pentavalent, Applicants have amended the formulas in claims 6 and 13 by using the dot lines inside the rings. Similar amendments have also been made to pages 6 and 7 of the specification. These amendments can be supported by the originally filed formula (I), wherein dot lines were used, and the formula (A) in the cited reference JP 8-119864 as would be appreciated by one of ordinary skill in the art to which the invention pertains. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record.

The rejection of claims 1-5 under 35 USC 102(b) as being anticipated by Takahashi et al. has been carefully considered but is most respectfully traversed in view of the cancellation of the claims from the present application. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1-5 under 35 USC 102(e) as being anticipated by Babish et al. has been carefully considered but is most respectfully traversed in view of the cancellation of the claims from the present application. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 6-13 under 35 USC 103(a) as being unpatentable over

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Takahashi et al. in view of Tai et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence presented by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

In this regard, Applicants most respectfully submit that the Examiner's interpretation of [0011] in the cited reference Takahashi is not correct as would be appreciated by one of ordinary skill in the art to which the invention pertains. The sediment from the fraction B was subjected to a reverse phase chromatography by using a methanol solution having a concentration of 90% as the solvent, to obtain the

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compound of formula 12 (33 mg), the compound of formula 13 (500 mg) and the compound of formula 14 (100 mg). *Poria* is extracted with methanol and the extract is 86.4 g. The percentage of the compounds having formulas 12-14 calculated is  $(33 \text{ mg} + 500 \text{ mg} + 100 \text{ mg})/86.4 = 0.73\%$ . Moreover, the extract further contains 0.12% of secolanostane (formula 16, 100 mg in Fraction D). Further, Takahashi teaches that secolanostane is a potent component as shown in Example 2, [0050], where the compound of formula 16, a secolanostane, is 10% by weight of a 200 mg tablet. Therefore, Takahashi does not suggest preparing a *Poria* extract comprising 5-60% of a lanostane having the following chemical formula (I) by weight of the extract, and being substantially devoid of secolanostane. That is Takahashi discloses purified compounds of formulas 12, 13, 14, and 16, and tablets containing a single purified compound. Even though the fraction B in Table 1 of Takahashi may be similar to the extract recited in claim 6 of the present invention, it is not known whether the fraction B is substantially devoid of secolanostane or not and whether the fraction B comprising 5-60% of a lanostane or not. Further, the fraction B is not concentrated to obtain an extract, to which  $\text{CHCl}_3$  is added to obtain a sediment, which is then subjected to a reverse phase chromatography to obtain purified compounds of formulas 12, 13, and 14.

Furthermore, Tai et al., discloses purified compounds of lanostanes and secolanostanes, and methods of purification. Again, Tai et al. does not suggest nor teach a *Poria* extract comprising 5-60% of a lanostane by weight of the extract, and being substantially devoid of secolanostane.

Applicants of the present application show the *Poria* extract (PCM-E in Example 2, PCM in Example 1) comprising 5-60% of a lanostane by weight of the extract and being substantially devoid of secolanostane is capable of enhancing immunity of human body. The extract containing secolanostanes, PCW-E in Example 2, is shown to be inhibitive as to the immunity of human body. For this reason, the present invention is non-obvious over the prior art and it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 6-13 under 35 USC 103(a) as being unpatentable over


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Babish et al. as applied to claims 1-5 above, in view of Cuellar et al. and Tai et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the above comments.

Furthermore, Babish et al. does not suggest a *Poria* extract; Cuellar et al. discloses purified compounds of pachymic acid and dehydrotumulosic acid, and methods of purification; and Tai et al. discloses purified compounds of lanostanes and secolanostanes. Accordingly, it is most respectfully request that this rejection be withdrawn.

In view of the above comments and further amendments to the specification and claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,  
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